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BIOMET MANUFACTURING CORP.

JAN 14 2011

510(k) Summary

Preparation Date: January 14, 2011

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Establishment Registration: 1825034

Contact Person:
Becky Earl
Regulatory Specialist

Proprietary Name: E1™ Avantage™ Head (a.k.a. E1™ Active Articulation)

Common Name: Artificial Hip Replacement Components--Acetabular

Classification Name:
LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)

OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (888.3358)

LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

KWY—Prosthesis, Hip, Hemi-Femoral, Metal/Polymer, Cemented (21 CFR 888.3390)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K072020	Restoration® ADM System—Howmedica Oseonics
K093644	Restoration® ADM System X3® Acetabular Insert—Howmedica Osteonics
K991990	Tri-Polar System—Biomet, Inc.
K070364	100 kGy E-Poly™ MaxRom™ Acetabular Liners—Biomet, Inc.
K070399	100 kGy E-Poly Acetabular Liners, Additional Sizes—Biomet, Inc.
K032396	RingLoc® 36mm Liners and Modular Femoral Heads-Biomet, Inc.
K083116	Versafit Cup Double Mobility System—Medacta International
K050327	E-Poly (Vitamin E) Acetabular Liners—Biomet, Inc.
K100048	E1™ Antioxidant Infused Technology—Biomet, Inc.

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E1™ Active Articulation
Biomet Manufacturing Corp.

Device Description:
The E1 Active Articulation™ belongs to the family of dual mobility acetabular implants: the presence of two articulating surfaces in the same joint device. The E1 Active Articulation™ Head fits over a femoral modular head, which articulates within the E1™ Head. The resultant assembly then articulates within the acetabular metal shell. The E1™ Head is designed to be used with several styles of acetabular shells that have been cleared in previous submissions: M²a Magnum™ (K042037), Magnum™ Tri-Spike (K062995), and M²a 38™ Flared Cups and Non-Flared Cups (K011110). The E1 Active Articulation™ Heads are available in sizes 44-66mm and are manufactured from 100 kGy E1™, which is the same 100 kGy E-Poly™ material cleared in K070364, The claims based on small punch testing for the K070364 E-Poly™ (E1™) material were cleared previously in K100048 and are applicable to the identical E-Poly™ (E1™) subject material. The E1™ Active Articulation is designed for both primary and total revision surgeries, where all device components associated with the wear couple are removed and replaced. The system is intended for uncemented applications.

FDA CLEARED CLAIMS[1] FOR E1™ ANTIOXIDANT INFUSED TECHNOLOGY[2]

Claim 1:
E1™ Antioxidant Infused Technology prevents oxidative degradation of polyethylene. Environmental stress crack testing was conducted by cyclically loading GUR1020 and GUR1050 E1™ test specimens in an air atmosphere maintained at 80°C for 5 weeks. Testing was completed per the literature (Nabar, Sean, et al. Transactions of the 54th Annual Meeting of the ORS, Poster No. 1684). E1™ specimens showed no evidence of environmental stress cracking and infrared spectroscopy showed no detectable oxidation in the loaded or unloaded samples (oxidation indices <0.1). E1 samples were machined from either GUR1020 (E1 knee) or GUR1050 (E1 hip) isostatically compression molded UHMWPE crosslinked with 100 kGy gamma irradiation under argon, doped with α-tocopherol, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 2:
E1™ Antioxidant Infused Technology protects polyethylene from oxidation and cracking during environmental stress crack testing. Environmental stress crack testing was conducted by cyclically loading test specimens in an air atmosphere maintained at 80°C for 5 weeks per the literature (Nabar, Sean, et al. Transactions of the 54th Annual Meeting of the ORS, Poster No. 1684). GUR1050 E1™ specimens ran head to head with GUR1050 gamma sterilized (25-40kGy in argon) polyethylene and sequentially crosslinked and annealed polyethylene (GUR 1050 barstock, 33kGy gamma irradiated in air, annealed at 130C in air and repeated for a total dose of 99kGy and machined into final part geometry). GUR1020 E1™ specimens ran head to head with GUR1050 direct compression molded polyethylene that was gamma sterilized (25-40kGy) in argon. The E1™ material was the only material tested that showed no evidence of environmental stress cracking or fracture and no detectable oxidation (oxidation indices <0.1) in the loaded and unloaded samples using infrared spectroscopy. Both gamma sterilized and sequentially crosslinked and annealed polyethylene showed evidence of increased oxidation and cracking or fracture during environmental stress crack testing. E1 samples were machined from either GUR1020 or GUR1050 isostatically compression molded UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 3:
E1™ Antioxidant Infused Technology maintains the mechanical strength of conventional UHMWPE under small punch testing. Small punch testing per ASTM F2183 was conducted for the E1™ hip material and the E1™ knee material. The E1™ hip material was compared to GUR1050 gamma sterilized in argon isostatic compression molded (ICM) UHMWPE and the E1™ knee material was compared to GUR1050 gamma sterilized (25-40kGy) in argon direct compression molded (DCM) UHMWPE. The ultimate load for the E1™ hip material and the GUR1050 ICM material are 105±5.5N and 75.4±5.3N respectively. The ultimate load for the E1™ knee material and the DCM control material are 97.2±6.4N and 86.6±7.5N respectively. The E1™ materials had ultimate loads greater than that of the ICM and DCM control. These differences were statistically significant ($p<0.001$ for all comparisons). E1 samples were machined

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from either GUR1020 (E1 knee) or GUR1050 (E1 hip) ICM UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 4 :
E1™ Antioxidant Infused Technology maintains mechanical strength after accelerated aging. There was no significant decrease (P>0.05) in ultimate load , ultimate tensile strength, or yield strength after accelerated aging for either the E1™ hip or the E1™ knee material. Ultimate load was measured by small punch testing per ASTM F2183; ultimate tensile strength and yield strength were measured by tensile testing per ASTM D638; Accelerated aging was performed per ASTM F2003 (70°C and 5 atm of oxygen for 14 days). The ultimate load for the E1™ knee material before and after accelerated aging was 97.2±6.4N and 100.0±5.0N respectively. The ultimate tensile strength for the E1™ knee material before and after accelerated aging was 45.8±1.6 and 46.1±2.9 MPa respectively. The yield strength for the E1™ knee material before and after accelerated aging was 22.6±0.2 and 22.8±0.3 MPa respectively. The ultimate load for the E1™ hip material before and after accelerated aging was 105.0±5.5N and 115.0±3.2N respectively. The ultimate tensile strength for the E1™ hip material before and after accelerated aging was 43±3 and 43±2 MPa respectively. The yield strength for the E1™ hip material before and after accelerated aging was 24.2±0.2 and 24.4±0.2 MPa respectively. E1 samples were machined from either GUR1020 (knee material) or GUR1050 (hip material) isostatically compression molded UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

1. *Cleared through 510(k) K100048*
2. *Note: E1™ Antioxidant Infused Technology may be used interchangeably with any of the following: E1™ Antioxidant Infused Bearings, E1™ Antioxidant Infused Material, E1™ material, E1™ technology, E1™ bearings, E1™ liners, E1™ acetabular liners and E1™ tibial bearings.*

Indications for Use:
1. Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.
6. Dislocation risks.

The E1™ Active Articulation is a single-use implant, intended for uncemented applications.

Summary of Technologies:
The E1™ Active Articulation Head has the same technological characteristics as the dual mobility predicates, with the exception that the UHMWPE material used is a 100kGy, Vitamin E infused polyethylene, which was previously cleared in K070364.

Non-Clinical Testing:
Wear, distraction testing of the bipolar portion (i.e., distraction of the UHMWPE from the femoral head), and Range of Motion testing were performed on the dual mobility subject device. The concentration and distribution of the Vitamin E in the E1™ Active Articulation Head material was determined. Results of the preclinical testing performed are within the range of legally marketed predicates and indicate that the device is functional within its intended use.

Clinical Testing:
None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corporation
% Ms. Becky Earl
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

JAN 14 2011

Re: K101336
Trade/Device Name: E1™ Avantage™ Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, OQG, LZO, KWY
Dated: January 10, 2011
Received: January 11, 2011

Dear Ms. Earl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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Device Name: E1™ Avantage™ Head

Indications For Use:

1. Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.
6. Dislocation risks.

The E1™ Avantage™ Head is a single-use implant, intended for uncemented applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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